EXHIBIT B

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Seattle, WA

Appeal of:	**VEIN AND WELLNESS GROUP LLC**	OMHA Appeal No.:	**3-5712725520**
Beneficiary:	**[Multiple]**	Medicare Part:	B
Medicare No.:	**[Multiple]**	Before:	**Andrea Barraclough** Administrative Law Judge

DECISION

After considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** decision issues for the physician's surgical services (billed under code 37241) that Appellant provided to the following beneficiaries on the following dates of service: beneficiary J.H. on date of service March 24, 2014 (claim # 9716293900423); beneficiary G.D. on dates of service April 8, 2014 (claim # 9716293900415), April 9, 2014 (claim # 9716293900416), April 10, 2014 (claim # 9716293900417); beneficiary J.L. on date of service April 17, 2014 (claim # 9716293900405); and S.D. on dates of service April 29, 2014 (claim # 9716293900346) and April 30, 2014 (claim # 9716293900347). Medicare shall cover and pay for the services at issue.

PROCEDURAL HISTORY

A. Case Events

Appellant sought reimbursement for surgical services under CPT code 37241. The Medicare Administrative Contractor (MAC) denied the claims at issue in redetermination decisions dated December 19, 2016 (File 10, pgs. 27-30), (File 10, pgs. 61-64), (File 10, pgs. 88-91); December 20, 2016 (File 10, pgs. 114-117); and December 28, 2016 (File 10, pgs. 140-143), (File 10, pgs. 167-170), (File 10, pgs. 194-197). On March 6, 2017, the Qualified Independent Contactor (QIC) denied the claims on reconsideration. File 2, pgs. 1-22. The QIC decision is an appealable initial determination per 42 C.F.R. § 405.920 and § 405.926.

On March 16, 2017, the Office of Medicare Hearings and Appeals (OMHA) received Appellant's timely request for a hearing by an Administrative Law Judge (ALJ), which met all jurisdictional requirements. File 1, pgs. 2-4. In its request for hearing, Appellant did not indicate that it had new evidence to present. *Id.*

Pursuant to proper notice, Appellant's hearing was conducted on June 15, 2021. Attorney Debra Parrish appeared as counsel for Appellant. No other parties appeared for the hearing. *Id.*

At the hearing, counsel for Appellant indicated that it appeared medical records had not been transmitted properly from the levels below. Because the medical records were required to reach a correct decision, the record was kept open after the hearing for submission of the additional medical evidence that Appellant's counsel believed were already in the redetermination and reconsideration records. *Id.* Additional medical evidence was submitted prior to the close of the record. This ALJ finds good cause to admit these records since Appellant believed they were included at earlier levels. Thus, there is good cause for admitting this evidence at the ALJ level under 42 C.F.R. § 405.1028(a)(2)(iv).

At the hearing, Exhibits (Files) 1-10 were admitted without objection. After the hearing, Exhibits (Files) 11 (Notice of Hearing), 12, 13 (Responses to Notice of Hearing), 14 (additional medical records), and 15 (the Hearing Audio) were administratively admitted. Thus, this ALJ enters and considers Exhibits (Files) 1 through 25 (excluding duplicates) in rendering this decision.

ISSUES

1. Were the physician's surgical services properly billed under CPT code 37214 such that they were covered and payable on the date of service?

2. If the services are not covered, do the limitation of liability provisions under Section 1879 of the Act or any other law apply? If not, who is financially responsible?

APPLICABLE LAW AND POLICY

I. Scope and Standard of Review

A. Scope of Review

The issues before the ALJ include all issues established in the initial, redetermined, or reconsidered claims and appeals that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a). The ALJ may decide a case on the record and not conduct a hearing if the Appellant and all other parties indicate in writing that they do not wish to appear before the ALJ. 42 C.F.R. § 405.1038. Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. 42 C.F.R. § 405.1046(a). The decision will be based on evidence offered at the hearing or otherwise admitted into the record. *Id.*

B. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and issues a decision based on the entirety of the hearing record. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act. *De novo* review requires the ALJ to review and evaluate all of the evidence without

regard to the findings or prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws.

The burden of proving each element of a Medicare claim lies with the Appellant, who must prove their case by a preponderance of the evidence. *See* Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; 42 C.F.R. § 424.5(a)(6), 42 C.F.R. § 405.1018, 42 C.F.R. § 405.1028, and 42 C.F.R. § 405.1030.

II. Applicable Law (Medicare Sections/ Regulations/Other Authority)

A. Authority

All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII and XIX of the Act, and all implementing Codes of Federal Regulations (CFRs) are binding on ALJs. 42 C.F.R. § 405.1063. National Coverage Determination (NCD) guidelines are also binding precedent for ALJs and are the only source of regulation that establishes or changes substantive legal standards governing the scope of Medicare benefits or payments. 42 C.F.R. § 405.1060.

The Centers for Medicare and Medicaid Services (CMS) and its contractors can and do issue non-binding policy guidance describing criteria for coverage of selected types of medical items and services in the form of manuals (CMS Manuals), local medical review policies (LMRPs), and Local Coverage Determinations (LCDs). ALJs will give substantial deference to LCDs, LMRPs, or CMS Manuals when applicable, and if they do not follow these policies, they must explain why in their decision. *See* 42 C.F.R. § 405.1062.

Prior decisions of the Medicare Appeals Council (the Council), which is the Level 4 appeals level for Medicare claims governed by the Departmental Appeals Board, are not binding unless the Chair of the Departmental Appeals Board deems them precedential. 42 C.F.R. § 405.1063. In all other cases, a decision of the Council may act as persuasive guidance from which the ALJ may depart at their discretion.

B. Medicare Generally

Sections 1831 and 1832 of the Act, and 42 C.F.R. § 410, establish the Supplemental Medical Insurance Program for the aged and disabled under Part B and outline Part B benefits and entitlements. Under § 1832(a)(2)(B) of the Act, Medicare will make direct payment to a medical or other health services provider or contractor that has provided medical services or equipment to a beneficiary. However, Medicare will not make payment unless sufficient information exists determining that the amount is proper and should be paid. 42 U.S.C. § 1395l, 42 C.F.R. § 424.5(6).

It is the responsibility of an Appellant to furnish sufficient information and documentation to support its claims for a Medicare payment. 42 C.F.R. § 424.5(a)(6). No adjudicator is under an obligation to seek additional documentation or supplement the record.

Section 1870 of the Act provides the authority for waiver of overpayments and other payment adjustments for incorrect payments on behalf of individuals. Overpayments shall not be recovered with respect to an individual who is "without fault." 42 U.S.C. § 1395gg.

C. Law Related to Condition and Service at Issue

1. Binding Authority - *Part B and Outpatient Services*

The Supplementary Medical Insurance program (Part B of Title XVIII of the Social Security Act) provides coverage for (1) a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, (2) for outpatient hospital services, and (3) for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium. The term "physicians' services" is defined in Section 1861(q) of the Act as professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6)[an intern or a resident-in-training]).

FINDINGS OF FACT AND ANALYSIS

After careful consideration of the entire record, a preponderance of the evidence establishes the following:

A. Factual Findings

Hearing Statements

1. At the hearing, Ms. Parrish argued that this case regards a Mechanical Occlusion Chemically Assisted Ablation (MOCA) treatment and whether CPT code 37241 was the appropriate code for the doctor to bill on the date of service. File 15, 6:40-14:30. The MOCA procedure was relatively new and did not yet have its own CPT code in 2014 and 2015. *Id.* Dr. Kelly O'Donnell (provider for Appellant company and client of Ms. Parrish) had been trained to use code 37241 in the absence of a specifically applicable code. *Id.* The actual on-point codes for MOCA (which are 364772 and 36473) did not come out until 2017. *Id.* The application process for getting a specific code generated for the MOCA procedure began in 2016. *Id.* In 2016, Novitas started visiting users of the MOCA procedure to tell them not to use code 37241 anymore, and to use the general surgery code 37999 in the interim until the MOCA-specific codes were approved. *Id.* Once Novitas told her to use the general surgery code, Dr. O'Donnell did, but this all happened in 2016, after the dates of service here. *Id.* The most appropriate code on the dates of service at issue was 37241, as it was closest to the actual procedure, so it was appropriate for Dr. O'Donnell use this code. *Id.*

2. Additionally, Ms. Parrish stated that the contractors seem to want to describe the procedure at issue as sclerotherapy, but such a characterization is not correct as the procedure is a MOCA procedure. *Id.* Ms. Parrish argued that the LCDs the contractors applied in this case (L32678,

and later L34924) were specific to sclerotherapy and did not apply to the MOCA procedure, so these LCDs could not be used to justify a denial. *Id.*

3. Ms. Parrish described the difference between the MOCA procedure and sclerotherapy. *Id.* In MOCA, a catheter is placed in the vein and the catheter turns around inside the vein to open it up; it is a non-thermal embolization method used in areas where there is a risk of nerve injury. *Id.* In sclerotherapy, medication is injected into the vein; it is primarily used for cosmetic purposes. *Id.* Also, sclerotherapy is used on small veins while MOCA is used on larger veins. *Id.* Here, the purpose of the procedure was not cosmetic, and the veins were large. *Id.* While some of the chemical agents used in both procedures can be the same, the goals and methods of each procedure are entirely different. *Id.*

Documentation for Beneficiary J.H.

4. The date of service at issue for beneficiary J.H. relevant to claim # 9716293900423 is March 24, 2014. File 10, pgs. 27-30.

5. The record shows the beneficiary underwent a MOCA procedure on March 24, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 14, pg. 7. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 39 cm of the beneficiary's right great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

Documentation for Beneficiary G. D.

6. The date of service at issue for beneficiary G.D. relevant to claim # 9716293900415 is April 8, 2014. File 10, pgs. 27-30.

7. The date of service at issue for beneficiary G.D. relevant to claim # 9716293900415 is April 9, 2014. *Id.*

8. The date of service at issue for beneficiary G.D. relevant to claim # 9716293900417 is April 10, 2014. *Id.*

9. The record shows the beneficiary underwent a MOCA procedure on April 8, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 14, pg. 3. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 25 cm of the beneficiary's left great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

10. The record shows the beneficiary underwent a MOCA procedure on April 9, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 14, pg. 5. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 15 cm of the beneficiary's left small saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

11. The record shows the beneficiary underwent a MOCA procedure on April 10, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 14, pg. 6. On the date of service, Dr.

O'Donnell conducted a MOCA procedure on 30 cm of the beneficiary's right great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

Documentation for Beneficiary J.L.

12. The date of service at issue for beneficiary J.L. relevant to claim # 9716293900405 is March 24, 2014. File 10, pgs. 27-30.

13. The record shows the beneficiary underwent a MOCA procedure on April 17, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 14, pg. 8. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 55 cm of the beneficiary's right great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

Documentation for Beneficiary S.D.

14. The date of service at issue for beneficiary S.D. relevant to claim # 9716293900346 is April 29, 2014. File 10, pgs. 27-30.

15. The date of service at issue for beneficiary S.D. relevant to claim # 9716293900347 is April 30, 2014. *Id.*

16. The record shows the beneficiary underwent a MOCA procedure on April 29, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 14, pg. 9. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 30 cm of the beneficiary's right great saphenous vein. *Id.* This record describes the procedure in detail. *Id.*

17. The record shows the beneficiary underwent a MOCA procedure on April 30, 2014, relevant to diagnosis code 454.8 Varicose Veins Leg. File 14, pg. 10. On the date of service, Dr. O'Donnell conducted a MOCA procedure on 27 cm of the beneficiary's right anterior accessory. *Id.* This record describes the procedure in detail. *Id.*

B. Analysis

1. Issue # 1 - Were the physician's surgical services properly billed under CPT code 37214 such that they were covered and payable on the date of service?

For all four beneficiaries, the MAC denied the services at issue, stating that the documentation did not meet the requirements of LCD L32678 or LCD L24924, and indicating that Dr. O'Donnell should have been performing an ablation rather than sclerotherapy. *See* File 10, pgs. 27-30. For all seven claim numbers, the QIC denied the services stating that the medical documentation was insufficient to support the codes billed. File 2, pgs. 1-22.

Appellant's argument is that the provider did, in fact, perform an ablation and not a sclerotherapy, such that the MAC was factually incorrect in applying either LCD L32678 or LCD

L24924. *See* File 12, Appellant Position Paper. Further, Appellant asserts that the coding used for the procedure was accurate at the time of the date of service. *Id.*

This record shows that Dr. O'Donnell indeed performed MOCA procedures on each patient, as opposed to sclerotherapy. *See* File 14, pgs. 1-10. While the surgical record documents mention the words "sclerotherapy volume," this refers only to a sclerotherapy agent that is used in the MOCA procedure, and not the actual procedure used. *See* File 15, 6:40-14:30.

Thus, LCD L32678, as cited by the MAC and as it existed in 2014, does not apply; this is because LCD L32678 does not address the MOCA procedure. Thus, inconsistent with the conclusion of the MAC, LCD L32678 cannot limit coverage in this case.[1] Thus, as there was no LCD on point on the dates of service for or any of these four beneficiaries, MOCA will be covered where it is generally medically reasonable and necessary.

This leaves the issue of whether CPT code 37241 was an appropriate code under which to bill. Based on the testimony and argument presented at the hearing, this ALJ finds credible that, in 2014, the MOCA procedure was a relatively new FDA-approved procedure for which an LCD had not yet been created and for which a CPT code had not yet been established. This ALJ finds credible that in the absence of an applicable CPT code, Dr. O'Donnell was using guidance from the manufacturer and a commercial insurer that code 37241 was the closest appropriate CPT code under which to bill the MOCA. Because there was no applicable policy that precluded the use of this code and the standard practice at the time for at least 50% of like surgeons and at least one commercial payer was to use this code, a preponderance of the evidence supports that the service at issue herein was validly coded. This is especially true where CMS did not tell Dr. O'Donnell to use CPT code 37999 until 2016, after the date of service in this case. Accordingly, this decision is favorable to Appellant.

2. Issue # 2- If the services were not covered, do the limitation of liability provisions under Section 1879 of the Act apply? If not, who is financially responsible?

As this decision is fully favorable to Appellant, no limited liability analysis is necessary.

CONCLUSIONS OF LAW

1. As to all beneficiaries (J.H., G.D., J.L., and S.D.) and all claims for all dates of service (March 24, 2014 for claim # 9716293900423); April 8, 2014, for claim # 9716293900415; April 9, 2014, for claim # 9716293900416; April 10, 2014, for claim # 9716293900417; April 17, 2014, for claim # 9716293900405; April 29, 2014, for claim # 9716293900346; and April 30, 2014, for claim # 9716293900347), because the general CPT code 37999 had not yet been the subject of instruction as the default CPT code pending approval of the eventual on-point CPT code for MOCA procedures, the

1LCD L32678 was retired on September 30, 2015, and replaced by LCD L24924, which was effective October 1, 2015, through December 31, 2016. Notably, L24924 was also related to sclerotherapy and not the MOCA specifically, rendering it too inapposite. The first instance of MOCA being added to any LCD did not occur until January 1, 2018, when it was added to LCD L33575.

physician's services billed by Appellant under CPT code 37241 for all the claims and dates of service are covered and payable by Medicare.

ORDER

For the reasons discussed above, this decision is **FULLY FAVORABLE.** The Medicare contractor shall process the claim in accordance with this decision.

SO ORDERED

Andrea R. Barraclough

Andrea Barraclough
Administrative Law Judge

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Seattle, WA

Appeal of: **VEIN AND WELLNESS GROUP LLC**	OMHA Appeal No.: **3-5712725520**
Beneficiary: **Multiple**	Medicare Part: **B**
Medicare No.: **Multiple**	Before: **Andrea Barraclough** Administrative Law Judge

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Exhibit Record	**Administrative File Reference**	
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Procedural - CMS Levels: Reconsideration, Beneficiary Copy	File 4	1 : 7
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To protect beneficiary privacy, names and references to other individuals have been removed from the beneficiary copies of the Administrative Record and Exhibit List.

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Exhibit Records for beneficiary S. DOLLE	**Administrative File Reference**	
	File Name	Page Range
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ATTACHMENT A

Beneficiary First Name	Beneficiary Last Name	Medicare No.
G.	D[redacted]	*****9562A
J.	L[redacted]	*****3955A
S.	D[redacted]	*****0555A
J.	H[redacted]	*****4192A